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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,042	04/21/2004	Trevor Barrowcliffe	674583-2001	7419
20999	7590	09/06/2006	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			ROOKE, AGNES BEATA	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/829,042

Applicant(s)

BARROWCLIFFE, TREVOR

Examiner

Agnes B. Rooke

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 9-12, 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 13-15 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/03/2006 has been entered.

The amendments to the claims filed on 08/03/2006 have been acknowledged.

Claims 1-18 are pending and claims 9-12 and 16-17 are withdrawn.

Claims 1-8, 13-15 and 18 are under examination.

**All Objections and Rejections not present in the instant office action have been  
withdrawn**

### **Claim Rejections**

#### ***35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since there is nothing linking these two compositions together, such as a kit comprising these two compositions, for example.

Applicants responded that these two compositions are to be administered at the same time but are mixed and/or not mixed prior to administration, thus the claim is clear.

Examiner disagrees and requires further specification of how these two compositions are admixed or combined prior to administration, since such a process cannot be performed in a vacuum.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 13-15, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lang et al. (U.S. 5,506,112).

Lang et al. teach a method where a mixture of factor IXa, and phospholipids is added to a sample containing factor VIII, thus activating factor VIII to be assayed; and where subsequently activated factor VIII forms complex with factor IXa. See column 1, lines 8-14.

Applicants stated that Lang does not anticipate the present claims because the present invention does not relate to assays for determining factor VIII activity; rather the invention relates to two pharmaceutical compositions, one containing IXa, the other containing coagulation factor VIII that are administered. Further, the language "consisting essentially of" overcomes the rejection.

Examiner maintains the rejection because the language of "consisting essentially of" and "comprising" is comparable and in this case does not narrow the claim. Also, Lang et al. teach a method where a mixture of factor IXa, and phospholipids is added to a factor VIII-containing sample, thus activating factor VIII to be assayed; and where subsequently activated factor VIII forms complex with factor IXa.

Further, Applicants state that Lang does not describe the use of two compositions that are administered to a subject who does not present with anti-FVIII antibodies, nor describes the use of two compositions for the treatment of hemophilia A or B.

Examiner disagrees because the rejected claims refer to a composition, and thus the use or administration of the composition is not relevant since any composition can be used for different purposes depending on a certain need; and also the claims refer to a method where the composition is made, and thus the administration of the composition is also irrelevant.

Claims 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Capon et al. (U.S. 4,965,199).

Capon et al. teach a method for producing factor VIII in recombinant mammalian host cell. See Abstract. Figure 1 teaches a step where factor IXa initiates the conversion of factor X to the activated form, factor Xa; where factor VIII is currently believed to function at this step in the presence of phospholipids and calcium ions as a cofactor and is required to enhance the activity of factor IXa; where this step, in a cascade, is critical since two most common hemophilia disorders have been determined to be caused by the decreased functioning of either factor VIII (hemophilia A or classic hemophilia) or factor IXa (hemophilia B).

Therefore, factor VIII is capable of catalyzing the conversion of factor X to Xa in the presence of factor IXa, calcium, phospholipids, as well as correcting the coagulation defect in plasma derived from hemophilia A affected individuals. See column 10, lines 27-32.

Claim 8 is included in this rejection because it depends from rejected independent base claim 4.

Prior art of Interest:

1. Barry et al., Proteolytic Interactions of Factor IXa Human Factor VIII and Factor VIIIa, Blood, vol. 80, no.12 (December 15), 1992, teach compositions of factor IXa and factor VIII in the presence and absence of a phospholipids, see Figure 1 on page 3121, for example.

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2. Elodi et al., Optimization conditions for the catalytic effect of the factor IXa-factor VIII complex, Thrombosis Research, 15, p. 617-629, 1979, teach composition of factor IXa with , see page 619. actor VIII.

### ***Objections to claims***

In claim 13, line 1, after the word "coagulation" the word "factor" should be inserted to read "coagulation factor VIII."

### ***Conclusion***

Claims 4-8 are allowable. Claims 1-3, 13-15 and 18 are not allowable.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

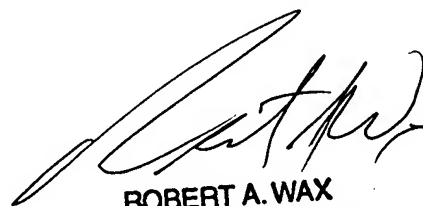
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-

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2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR



ROBERT A. WAX  
PRIMARY EXAMINER